

FUNAMIZU et al
Appl. No. 09/485,845
February 12, 2004

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REMARKS/ARGUMENTS

Reconsideration of this application and entry of this Amendment are solicited. Claims 67-76 and 85 remain pending in the application.

Responsive to item 1 of the Official Action, the compounds falling within non-elected subject matter have been deleted from claim 67. For the examiner's convenience attached is a copy of claim 67 showing the deletions and also giving the numbers of the relevant examples related to each of the compounds listed in this claim.

In addition, a typing error has been noted in the fourth compound of page 6 of the previous response, namely the substituent should be an 8-fluoro which is consistent with the description found on pages 47-48 of the specification relating to compound 91. No new matter is involved with this change, simply a typing correction.

Responsive to item 3 of the Official Action, claim 69 has been amended in order to reduce issues.

This leaves for consideration the issues raised in item 4 of the Official Action in which it is argued that claim 85 includes subject matter "which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention."

With respect, when one considers all of the information in the as-filed specification it will be apparent that the inventors did indeed contemplate a series of compounds and homologues which include the structures noted by the examiner in item 4 of the Official Action, namely one of the moieties for definition A₁ as well as for the definition of D. For instance, with respect to A₁ it will be noted that on page 13 of the Amendment and response of September 2, 2003, three structures are given in which the first contains no substitution on the sulfur atom, the second contains a single substitution and the third contains two substitutions.

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The same series of homologues is also shown on the same page at lines 2 and 3 where there is no substitution, a single substitution and a double substitution of oxygen on the sulfur atom. Other structures with homologous variants are throughout the specification and the same pertains to the structures shown for the definition D on page 14 of the Amendment and response of September 2, 2003.

Not only were applicants working in homologous series, some of the compounds falling within the particular series being investigated turned out to be highly effective and in fact were identified at the time of filing as being preferred compounds. The fact that general structures were (for inadvertence or otherwise) not specifically listed in original claim 10, for instance, appropriate structures are provided throughout the specification, particularly in the tables, as to other components. Thus the totality of the description of the invention should be considered in assessing and reviewing the examiner's position.

As stated in the Amendment and response filed September 2, 2003, the compounds in Example Nos. 67 and 68 on page 45 of the present specification have 1,4-dioxo-2,3-dihydro-benzol[1,5]thiazepine as the "A₁" substituent, and the compound in Example No. 172 (the last compound on page 62) has as the "D" substituent the structure: -NH-CH₂-CH(OH)-CH₂-NH-CH₂-CH(OH)-CH₃.

The compound in Example No. 68 is specifically listed in page 17, lines 9-10 as a preferred compound.

The compound in Example No. 172 is also listed in page 19, lines 20-21 as a preferred compound. The paragraph on page 37, lines 11-15 states that (among others) the compound in Example 68 exhibits excellent growth hormone releasing activity.

When all of the relevant information is considered, especially that summarized above, it will be apparent that claim 85 correctly and adequately reflects the inventive contributions of applicants, is free from the prior art and is fairly based upon the description of the invention as filed.

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Reconsideration and favorable action are solicited.

Respectfully submitted,

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AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-66 cancelled.

(67). (Previously Presented) A compound selected from:

73 N-(2-Aminoethyl)-3-phenyl-2(R)-[2-(1,1,4-trioxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)-acetyl-amino]propionamide;

X 94 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(2-oxo-2,3,4,5-tetrahydro-benzo[b]azepin-1-yl)propionamide;~~

X 101 ~~3-(3-Acetyl-amino-2-oxo-2,3,4,5-tetrahydro-benzo[b]azepin-1-yl)-N-[1(R)-(2-amino-ethylcarbamoyl)-2-(naphthalen-2-yl)ethyl]propionamide;~~

X 158 ~~N-[1(R)-(2-Aminoethylcarbamoyl)-2-(naphthalen-3-yl)ethyl]-3-(6-oxo-11,12-dihydro-6H-dibenzo[b,f]azocin-5-yl)propionamide;~~

X 159 ~~N-[1(R)-(3-Amino-propylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(6-oxo-11,12-dihydro-6H-dibenzo[b,f]azocin-5-yl)propionamide;~~

1 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(4-oxo-2,3-dihydro[1,5]benzothiazepin-5-yl)propionamide;

6 N-[1(R)-(4-Aminobutylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)propionamide;

4 N-(4-Aminobutyl)-3-(naphthalen-2-yl)-2(R)-[2-(4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)-acetyl-amino]propionamide;

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126 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(11-oxo-11H-dibenzo[b,f][1,4]oxazepin-10-yl)propionamide;

X 108 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(5,11-dioxo-2,3-dihydro-11H-(11a5)pyrrolo[2,1-e][1,4]benzodiazepin-10-yl)propionamide;~~

X 96 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(6-methoxy-2-oxo-2,3,4,5-tetrahydro-benzo[b]azepin-1-yl)propionamide;~~

10 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)butyramide;

X 109 ~~N-[1(R)-(4-Aminobutylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(4-methyl-2,5-dioxo-2,3,4,5-tetrahydro-benzo[c][1,4]diazepin-1-yl)propionamide;~~

X 122 ~~N-[1(R)-(2-Aminoethylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(3-oxo-2,3-dihydro-benzo[1,4]oxazin-4-yl)propionamide;~~

X 123 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(3-oxo-2,3-dihydro-benzo[1,4]oxazin-4-yl)propionamide;~~

X 115 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(2-oxo-3,4,5,6-tetrahydro-2H-benzo[b]azocin-1-yl)propionamide;~~

44 N-(2-Amino-2-methylpropyl)-3-(naphthalen-2-yl)-2(R)-[3-(4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)-propionylamino]propionamide;

79 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(2-methyl-4-oxo-2,3-dihydro[1,5]benzothiazepin-5-yl)propionamide;

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X 129 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(6-oxo-11,12-~~
~~-dihydro-6H-dibenzo[b,f]azocin-5-yl)butyramide;~~

X 121 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-3-(naphthalen-2-yl)ethyl]-4-(3-oxo-2,3-~~
~~-dihydro-benzo[1,4]thiazin-4-yl)butyramide;~~

19 N-[1(R)-(3-Methylamino-propylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(4-oxo-
2,3-dihydro-[1,5]benzothiazepin-5-yl)propionamide;

20 N-[1(R)-(3-Methylamino-propylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(4-oxo-
2,3-dihydro-[1,5]benzothiazepin-5-yl)butyramide;

42 N-(1(R)-[(3-Aminopropyl)-methylcarbamoyl]-2-(naphthalen-2-yl)ethyl)-4-(4-oxo-
2,3-dihydro-[1,5]benzothiazepin-5-yl)butyramide;

134 N-(3-Amino-2-hydroxypropyl)-3-(naphthalen-2-yl)-2(R)-[3-(4-oxo-2,3-dihydro-
[1,5]benzothiazepin-5-yl)-propionylamino]propionamide;

135 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(4-
oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)butyramide;

9 N-[1(R)-(2-Amino-ethylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(4-oxo-2,3-
dihydro-[1,5]benzothiazepin-5-yl)butyramide;

28 N-(1(R)-[Bis-(3-aminopropyl)carbamoyl]-2-(naphthalen-2-yl)ethyl)-4-(4-oxo-2,3-
dihydro-[1,5]benzothiazepin-5-yl)butyramide;

72 N-[1(R)-(3-Amino-propylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(1,1,4-trioxo-
2,3-dihydro-[1,5]benzothiazepin-5-yl)butyramide;

127 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(11-oxo-11H-

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dibenzo[b,f][1,4]oxazepin-10-yl)butyramide;

X 112 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-3-yl)ethyl]-3-phenothiazin-10-yl propionamide;~~

X 160 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(6-oxo-11,12-dihydro-6H-dibenzo[b,f]azocin-5-yl)propionamide;~~

X 140 ~~N-(3-Amino-2-hydroxypropyl)-2(R)-[3-(6-methoxy-2-oxo-2,3,4,5-tetrahydrobenzo[b]azepin-1-yl)propionylamino]-3-(naphthalen-2-yl)propionamide;~~

X 155 ~~N-(3-Amino-2-hydroxypropyl)-3-(naphthalen-2-yl)-2(R)-[3-(2-oxo-2,3,4,5-tetrahydrobenzo[b]azepin-1-yl)propionylamino]propionamide;~~

X 144 ~~N-(3-Amino-2-hydroxypropyl)-3-(naphthalen-2-yl)-2(R)-[3-(3-oxo-3,4,5,6-tetrahydro-2H-benzo[b]azocin-1-yl)propionylamino]propionamide;~~

15 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-5-(4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)pentanamide;

14 N-[1(R)-(2-aminoethylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-5-(4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)pentanamide;

58 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(1H-indol-3-yl)-ethyl]-4-(4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)butyramide;

64 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(5,6,7,8-tetrahydro-naphthalen-2-yl)ethyl]-4-(4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)butyramide;

145 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(11-oxo-11H-dibenzo[b,f][1,4]oxazepin-10-yl)propionamide;

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68 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(1,4-dioxo-2,3-dihydro-[1,5] benzothiazepin-5-yl)butyramide;

107 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(4-oxo-2,3-dihydro-[1,5]-benzoxazepin-5-yl)butyramide;

152 N-[1(R)-(3-Amino-2-hydroxypropylcarbamyl)-2-(naphthalen-2-yl)ethyl]-3-(2-methyl-4-oxo-2,3-dihydro[1,5]benzothiazepin-5-yl)propionamide;

91 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(7-fluoro-4-oxo-[1,5]benzothiazepin-5-yl)propionamide;

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X 146 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(5,11-dioxo-2,3-dihydro-1H,11a5)pyrrolo[2,1-c][1,4]diazepin-10-yl)propionamide;~~

X 147 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(phenothiazin-10-yl)propionamide;~~

X 141 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(6-methoxy-2-oxo-2,3,4,5-tetrahydro-benzo[b]azepin-1-yl)butyramide;~~

89 N-[1(R)-(2-Aminoethylcarbamoyl)-2-(naphthalene-2-yl)ethyl]-3-(8-fluoro-4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)propionamide;

138 N-(3-Amino-2-hydroxypropyl)-3-(naphthalene-2-yl)-2(R)-[3-(4-oxo-7-trifluoromethyl-2,3-dihydro-[1,5]benzothiazepin-5-yl)propionylamino]propionamide;

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- 143 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(4-oxo-2,3-dihydro-[1,5]-benzoxazepin-5-yl)butyramide;
- 142 N-(3-Amino-2-hydroxypropyl)-3-(naphthalen-2-yl)-2(R)-[3-(4-oxo-2,3-dihydro-[1,5]-benzoxazepin-5-yl)propionylamino]propionamide;
- 137 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(8-fluoro-4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)butyramide;
- 136 N-(3-Amino-2-hydroxypropyl)-2(R)-[3-(8-fluoro-4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)propionylamino]-3-(naphthalen-2-yl)propionamide;
- 92 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(8-fluoro-4-oxo-[1,5]-benzothiazepin-5-yl)butyramide;
- X 200 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(6-oxo-6,11-dihydro-dibenzo[b,e]azepin-5-yl)propionamide;~~
- X 236 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(6-oxo-6,11-dihydro-dibenzo[b,e]azepin-5-yl)propionamide;~~
- X 205 ~~N-[1(R)-(2-Aminoethylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(6,11-dioxo-6,11-dihydro-dibenzo[b,e]azepin-5-yl)propionamide;~~
- X 206 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(6,11-dioxo-6,11-dihydro-dibenzo[b,e]azepin-5-yl)propionamide;~~
- X 242 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(6,11-dioxo-6,11-dihydro-dibenzo[b,e]azepin-5-yl)propionamide;~~

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X 130 ~~N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-5-(6-oxo-6H-~~
~~dibenzo[b,f]azocin-5-yl)pentanamide;~~

X 241 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-5-(6-~~
~~oxo-6H-dibenzo[b,f]azocin-5-yl)pentanamide;~~

216 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(11-oxo-11H-
dibenzo[b,f][1,4]thiazepin-10-yl)propionamide;

244 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(11-
oxo-11H-dibenzo[b,f][1,4]-thiazepin-10-yl)propionamide;

249 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-5-
(5,11-dioxo-5,11-dihydrodibenzo-[b,f][1,4]thiazepin-10-yl)pentanamide;

252 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-5-
(5,5,11-trioxo-5,11-dihydro-dibenzo[b,f][1,4]thiazepin-10-yl)pentanamide;

255 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(2,2-
dimethyl-4-oxo-3,4-dihydro-2H-benzo[1,5]thiazepin-5-yl)propionamide;

X 259 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(7-~~
~~chloro-5,11-dioxo-2,3,11,11a-tetrahydro-11H-5H-benzo[c]pyrido[1,2-~~
~~a][1,4]diazepine-10-yl)propionamide;~~

X 264 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-~~
~~(6,12-dioxo-6,6a,7,8,9,10-hexahydro-12H-benzo[e]pyrido[1,2-a][1,4]diazepine-5-~~
~~yl)propionamide;~~

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X 258 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(9-fluoro-2-oxo-3,4,5,6-tetrahydro-2H-benzo[b]azecin-1-yl)propionamide;~~

165 N-[1(R)-(3-Aminopropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-2-methyl-3-(4-oxo-3,4-dihydro-2H-benzo[1,5]-thiazepin-5-yl)propionamide;

253 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-2-methyl-3-(4-oxo-3,4-dihydro-2H-benzo[1,5]thiazepin-5-yl)propionamide;

182 N-[1(R)-(3-amino-2(S)-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(4-oxo-3,4-dihydro-[1,5]-benzothiazepin-5-yl)butyramide;

X 262 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-2-methyl-3-(5,11-dioxo-2,3,11,11a-tetrahydro-1H,5H-benzo[c]pyrrolo[1,2-a][1,4]diazepine-10-yl)propionamide;~~

181 N-[1(R)-(3-amino-2(R)-hydroxy-propylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-4-(4-oxo-3,4-dihydro-[1,5]-benzothiazepin-5-yl) butanamide;

X 263 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-2,3-dimethyl-3-(5,11-dioxo-2,3,11,11a-tetrahydro-1H,5H-benzo[c]pyrrolo[1,2-a][1,4]diazepine-10-yl)propionamide;~~

257 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-2,2-dimethyl-3-(1,1,4-trioxo-benzo-[1,5]thiazepin-5-yl)propionamide;

164 N-[1(R)-(2-Amino-ethylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-2-methyl-3-(4-oxo-3,4-dihydro-[1,5]benzothiazepin-5-yl)propionamide;

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254 N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(4-oxo-3,4-dihydro[1,5]benzothiazepin-5-yl)butyramide;

X 268 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(3-cyano-5-isopropyl-2-oxo-2H-cyclohepta-4,6,8-trieno[5,6]pyrrol-1-yl)propionamide;~~

X 260 ~~N-[1(R)-(3-Amino-2-hydroxypropylcarbamoyl)-2-(naphthalen-2-yl)ethyl]-3-(5,11-dioxo-2,3,11,11a-tetrahydro-1H,5H-benzo[6,7]pyrrolo[1,2-a][1,4]diazepin-10-yl)propionamide; and~~

172 N-[1(R)-[2-Hydroxy-3-(2(R)-hydroxypropylamino)propylcarbamoyl]-2-naphthalen-2-yl-ethyl]-4-(4-oxo-2,3-dihydro-[1,5]benzothiazepin-5-yl)butyramide.

68. (Previously Presented) A composition which comprises an inert carrier and a compound according to claim 85.

69. (Previously Presented) A composition which comprises an inert carrier, a compound according to claim 85 and at least one of the following components:
 a growth hormone secretagogues selected from KP-102(GHRP-2), GHRP-6, Hexarelin, and GHRP-1,
 a growth hormone releasing factor (GRF) selected from IGF-1, IGF-2 and B-HT920, and
~~a growth hormone~~ ✓

70. (Previously Presented) A method for increasing levels of endogenous growth hormones in a human or an animal which comprises administering to such human or animal an effective amount of a compound according to claim 85.